

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Boule Medical AB
Domnarvsgatan 4,
SE-163 53
Spånga
Sweden

Holds Certificate Number:

MD 717615

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The development, manufacturing, marketing, servicing, and distribution of laboratory systems for clinical diagnostics.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-09-24

Latest Revision Date: 2019-09-24

Effective Date: 2019-09-24

Expiry Date: 2022-05-20

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Certificate No: **MD 717615**

Location

Boule Medical AB
Domnarvsgatan 4,
SE-163 53
Spånga
Sweden

Boule Medical AB
Fagerstagatan 7,
SE-163 53
Spånga,
Sweden

Registered Activities

The development, manufacturing, marketing, servicing, and distribution of laboratory systems for clinical diagnostics.

The manufacturing of laboratory systems for clinical diagnostics.



Original Registration Date: 2019-09-24

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:

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